

Appln. Serial No. 10/530,087
Filed: January 30, 2006
Docket No.: 8932-1091-999
CAM No.: 232200-999280

Amendments to the Drawings:

The attached replacement drawing sheet includes a minor amendment to FIG. 2. FIG. 2 has been amended to remove reference character "2," which was used to denote a different feature in FIG. 1. No new matter has been added. The attached APPENDIX C includes one (1) clean, clearly labeled Replacement Sheet.

Attachment: Replacement Sheet (1)

REMARKS

This amendment is submitted in response to the non-final Office Action mailed July 27, 2006. Following entry of this amendment, claims 1-20 will be pending in this application. Claims 1 and 18 are independent. In the Office Action, the Examiner:

- objected to the drawings because reference numeral 2 was used to denote two different elements in FIGS. 1 and 2, respectively, and because reference numeral 18' (shown in FIG. 2) was not mentioned in the specification;
- objected to the Abstract as being written in claim format and for using a phrase that "implies";
- objected to claims 5-14 as multiple dependent claims dependent from other multiple dependent claims;
- rejected claims 2-4 under 35 U.S.C. § 112, second paragraph; and
- rejected pending claims 1-4 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,356,410 to Pennig (hereinafter "Pennig") in view of U.S. Patent No. 5,562,667 to Shuler (hereinafter "Shuler").

Applicants have amended claims 1-14 and added new claims 15-20 to further define the invention recited, more clearly distinguish over the cited prior art, remove multiple dependencies, and/or conform with amendments to other claims. All amendments are fully supported by the originally-filed specification and/or drawings of the present application. No new matter has been added. The claim amendments made herein do not represent acquiescence in the Examiner's rejections, but rather are made only to expedite prosecution of the present application and/or maintain consistency in claim language. Applicants expressly reserve the right to pursue the subject matter of any previously presented claims in one or more continuation applications. As discussed more fully below, Applicants respectfully submit that each of the currently pending claims define features that are not disclosed, taught or suggested by the prior art of record and respectfully requests allowance of same.

Drawings

The Examiner objected to the drawings for using reference numeral 2 to denote two

different elements and because reference numeral 18' was not mentioned in the specification. In response, applicants have submitted an amended FIG. 2, which removes reference numeral 2, and have amended the specification to make reference to numeral 18', which denotes the projection of the transverse borehole axis 18. No new matter has been added. Given these amendments, applicants respectfully request withdrawal of the drawing objections.

Abstract

The Examiner objected to the Abstract as using a phrase that implies, e.g., "The invention relates . . .", and as being written in claim format. In response, applicants have amended the abstract to remove the offending phrase and to appear in narrative form, rather than claim format. Given these amendments, applicants respectfully request withdrawal of the objections to the abstract.

Claim Objections

Claims 5-14 were objected to as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. Applicants have amended the claims so that there are no longer any multiple dependent claims which depend on any other multiple dependent claim. Given these amendments, applicants respectfully request that the claim objections be withdrawn.

Claim Rejections 35 U.S.C. §112

Claims 2-4 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Specifically, claims 2 and 3 both claimed a broad range together with a narrow range falling within the broad range within the same claim. Claim 4 was dependent upon claims 2 and 3. In response, applicants have amended claims 2 and 3 so that each of claims 2 and 3 now only recite a single range. Amended claim 7 and new claim 16 recite the narrow ranges originally included in claims 2 and 3. No new matter has been added.

Claim 2 was also rejected under 35 U.S.C. § 112, second paragraph, because the Examiner was unclear if the limitation stating that the center of gravity of the angled tab of the bone plate, if projected onto a cross-sectional area orthogonal to the longitudinal axis of the medullary pin, lies on a radius which encloses in this cross-sectional area an angle β of between 0° and $+100^\circ$ relative to a projection of the transverse borehole axis is a limitation

applying to the bone plate. As presently advised, the Examiner has treated this portion of claim 2 as functional language and *not* a limiting characteristic of the bone plate. Claim 3 has been similarly rejected.

Applicants respectfully submit that claims 2 and 3 make clear that the language referred to by the Examiner is a structural limitation of the bone plate, *not* functional language. The limitation specifies the relationship between the structural characteristics of the bone plate and the intramedullary pin, i.e., that a projection of the center of gravity of the angled tab of the bone plate onto a cross sectional area taken orthogonal to the longitudinal axis of the pin lies on a radius, originating from the longitudinal axis of the pin, forming an angle of between +0° and +100° relative to the projection of the transverse borehole axis onto the same orthogonal cross-sectional area.

Given these amendments and remarks, applicants respectfully request withdrawal of the indefiniteness rejections of claims 2-4.

Claim Rejections 35 U.S.C. § 103(a)

Claims 1-4 were rejected as obvious under 35 U.S.C. § 103(a) in view of Pennig in combination with Shuler. Applicants respectfully traverse each of these claim rejections and submit that claims 1-4 distinguish over the cited prior art.

With regard to claim 1, the Examiner admits that Pennig fails to disclose an intramedullary pin with a transverse borehole in the proximal end of the pin and also fails to disclose that the bone plate ends proximally above the transverse boreholes in the proximal end of the pin. (July 27, 2006 Office Action in Appln. Ser. No. 10/530,087 at 7 (hereinafter “Office Action”).) The Examiner states that “[i]t would have been obvious to one having ordinary skill in the art at the time of the invention to manufacture the intramedullary pin of Pennig with the transverse boreholes of Shuler in order to receive interlocking screws.” (Id. at 7.) But the Examiner fails to make a prima facie case of obviousness for at least three reasons — (1) the Examiner fails to provide any actual motivation to combine Pennig with Shuler, (2) Pennig teaches away from the use of transverse boreholes in the intramedullary pin, and (3) adding transverse boreholes to Pennig would change the principle of operation of the Pennig device.

First, the statement in the Office Action that “[i]t would have been obvious to one having ordinary skill in the art at the time of the invention to manufacture the intramedullary pin of Pennig with the transverse boreholes of Shuler in order to receive interlocking screws”

is effectively a conclusory statement that it would have been obvious to combine two elements, i.e., the pin of Pennig with the boreholes and associated screws of Shuler.

According to the MPEP,

A statement that modifications of the prior art to meet the claimed invention would have been 'well within the ordinary skill of the art at the time the claimed invention was made' because the references relied upon teach that all aspects of the claimed invention were individually known in the art is not sufficient to establish a prima facie case of obviousness without some objective reason to combine the teachings of the references.

MPEP § 2143.01, Section IV (citing *Ex parte Levensgood*, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993)) (emphasis in original). In the present case, the Examiner has not provided an objective reason to combine the teachings of the references.

In addition to the fact that there is no motivation in Pennig or Shuler to combine those references to arrive at the device recited in amended claim 1, Pennig explicitly teaches away from the combination with Shuler suggested in the Office Action. As stated in the MPEP, "[i]t is improper to combine references where the references teach away from their combination." MPEP § 2145, Section X.D.2 (citing *In re Grasselli*, 713 F.2d 731, 743 (Fed. Cir. 1983).) Pennig teaches that:

The osteosynthesis plate features a plurality of holes for the accommodation of bone screws, the transverse spacing of the holes being greater than the diameter of the medullary nail, *so that the direction of the bone-screw orientation is not predetermined by corresponding accommodating bores in the medullary nail*. As a consequence, bone screws through the holes in the plate may bypass the medullary nail on both sides and lead to the head of the femur, in that the direction of bone-screw advance is *freely selectable*.

(Pennig at col. 1:56-65.) Therefore, Pennig clearly teaches that the direction of bone-screw advance into the femoral head be *freely-selectable*, and *not* predetermined by bores in the medullary nail. Therefore, Pennig teaches away from the proposed combination with Shuler, which would add predetermined bores to the medullary nail of Pennig and directly contradict Pennig's disclosure that the direction of bone-screw advance be *freely selectable*.

Similarly, modifying Pennig as suggested in the Office Action would change the principle of operation of the Pennig device. "If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teaching of the references are not sufficient to render the claims *prima facie* obvious." MPEP § 2143.01, Section VI (citing *In re Ratti*, 270 F.2d 810 (CCPA 1959). IN

addition to the disclosure in Pennig discussed above concerning “freely selectable” insertion paths for the Pennig bone screws, Pennig further teaches that “the osteosynthesis plate is equipped with holes designed to accommodate bone screws, and *these holes are so arranged that the bone screws can bypass the medullary nail.*” (Pennig at col. 2:8-11.) Therefore, the Pennig device is expressly designed so that the bone screws *avoid* the medullary nail. Consequently, modifying Pennig so that the bone screws pass through the medullary nail would change the basic principle of operation of the Pennig device.

For each of these reasons, the Office Action fails to make a prima facie case of obviousness based on the combination of Pennig with Shuler. Accordingly, applicants respectfully request that the obviousness rejections of claims 1-4 be withdrawn, and that those claims, and each of their dependent claims, be allowed.

In addition, applicants respectfully disagree with the Examiner’s conclusion that “[i]t would have been an obvious matter of design choice to change the size of the bone plate [of Pennig] to have it end proximally above the transverse borehole in the proximal end of the pin, since such a modification would have involved a mere change in the size of a component.” (Office Action at 7.) Applicants respectfully submit that, due to the anatomy of the femur and surrounding muscles, a person of ordinary skill in the art would appreciate that the proposed modification would alter the functionality and operation of the bone plate. Consequently, the proposed modification of the bone plate — a key element of the claimed invention — requires the consideration of more than just the “mere change in the size of a component” suggested in the Office Action. Accordingly, for this additional reason, the obviousness rejection of claim 1, and its dependent claims, should be withdrawn.

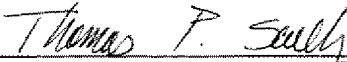
In view of the above amendments and remarks, Applicants respectfully request that the Examiner reconsider pending claims 1-20 with a view towards allowance. The Examiner is invited to call the undersigned attorney at (212) 326-3939 if a telephone call could help resolve any remaining issues.

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A separate petition for a two-month extension of time is submitted herewith. No additional claim fees are believed due. However, should any additional fees be required, please charge such fees to Jones Day deposit account no. 50-3013.

Respectfully submitted,

Dated: December 27, 2006



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